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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,996	01/13/2004	Peter M. Bonutti	780-A03-021-5	1472

33771 7590 03/12/2007  
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS,  
GUTMAN, BONGINI, & BIANCO P.L.  
21355 EAST DIXIE HIGHWAY  
SUITE 115  
MIAMI, FL 33180

EXAMINER

HOFFMAN, MARY C

ART UNIT PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/755,996

Applicant(s)

BONUTTI, PETER M.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-10,13,15,19-22 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,13,15,19-22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

Upon further consideration, the finality of the office action mailed 12/29/2006 has been withdrawn.

#### ***Allowable Subject Matter***

The indicated allowability of claims 20-22 and 25-26 is withdrawn. A new rejection follows.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-9, 13, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Kovaleva et al. (U.S. Patent No. 4,298,993).

Stone discloses an implantable device for changing the spatial relationship between first and second bones comprising a body (see FIG. 4a), wherein the body includes bone-contacting first and second major planar surfaces, and a side surface there between and wherein one major surface tapers to form a pointed edge with the

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other major surface. The body has an open cellular structure to provide cavities in which bone can grow through (col. 6, lines 34-36). The body is made of a biocompatible metallic material (col. 6, lines 44-46). At least some of the cavities contain a bone growth promoting material (col. 7, lines 8-14). A portion of the side surface has a configuration corresponding to at least a section of an outer side surface of one of the first and second bones.

Stone discloses the claim invention except for the device being coated with a bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, and a first channel extending through the first major surface and side surface, and a screw angularly disposed in the first channel.

Michelson discloses using a coating of bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, in order to promote bioactive fusion (col. 9, lines 20-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with the coating of Michelson in order to promote bioactive fusion.

Kovaleva et al. discloses an implantable device including a first channel extending through the first major surface and side surface, and a screw angularly disposed in the first channel (ref. #11/12) in order to fix the implant to the bone, and the screw holes can also be used with a special holder (col. 3, line 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with a first channel extending

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through the first major surface and side surface, and a screw angularly disposed in the first channel in order to fix the implant to the bone, and also to provide holes that can be used with a special holder.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Kovaleva et al. (U.S. Patent No. 4,298,993) and further in view of Jefferies (U.S. Patent No. 4,394,370).

Stone in view of Michelson discloses the claimed invention except for the coating being apatite compositions such as demineralized bone powder and collagen.

Jefferies teaches both demineralized bone powder and collagen as materials to induce the formation of osseous tissue (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the coating of the Stone in view of Michelson and Kovaleva et al. to include demineralized bone powder and collagen in view of Jeffries, since those materials are well known in the art of bone fusion as materials to induce the formation of osseous tissue.

Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Kovaleva et al. (U.S. Patent No. 4,298,993) further in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

Stone in view of Michelson and Kovaleva et al. discloses open cellular and biocompatible material, including metals, but does not specifically disclose tantalum.

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Zdeblick et al. teaches using porous tantalum in implants to allow bone ingrowth. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone in view of Michelson and Kovaleva et al. using tantalum in view of Zdeblick et al. to allow bone ingrowth.

Claims 20-22 and 25-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Henderson et al. (U.S. Patent No. 6,066,175).

Stone discloses an implantable device for changing the spatial relationship between first and second bones comprising a body (see FIG. 4a), wherein the body includes bone-contacting first and second major planar surfaces, and a side surface there between and wherein one major surface tapers to form a pointed edge with the other major surface. The body has an open cellular structure to provide cavities in which bone can grow through (col. 6, lines 34-36). The body is made of a biocompatible metallic material (col. 6, lines 44-46). At least some of the cavities contain a bone growth promoting material (col. 7, lines 8-14). A portion of the side surface has a configuration corresponding to at least a section of an outer side surface of one of the first and second bones.

Stone discloses the claim invention except for the device being coated with a bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, and a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and screws angularly disposed in the channels.

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Michelson discloses using a coating of bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, in order to promote bioactive fusion (col. 9, lines 20-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with the coating of Michelson in order to promote bioactive fusion.

Henderson et al. disclose an implantable device including a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and screws angularly disposed in the channels in order to provide means of attachment to the bone (ref. #48, 49, FIGS. 8-9, col. 9, lines 29-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and screws angularly disposed in the channels in order to provide means of attachment to the bone.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Henderson et al. (U.S. Patent No. 6,066,175) further in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

Stone in view of Michelson and Henderson et al. discloses open cellular and biocompatible material, including metals, but does not specifically disclose tantalum.

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Zdeblick et al. teaches using porous tantalum in implants to allow bone ingrowth. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone in view of Michelson and Henderson et al. using tantalum in view of Zdeblick et al. to allow bone ingrowth.

### ***Response to Arguments***

Applicant's arguments filed 02/28/2007 have been fully considered but they are not persuasive.

Applicant argues that "Kovaleva fails to disclose a screw hole extending through either the convex 4 or concave 5 surfaces and a side surface of the implant." The examiner respectfully disagrees, since the specification of the reference clearly states that the holes ref. #12 open into the base ref. #6 (i.e. the side surface) and into the convex surface ref. #4 (see in column 3, lines 24-29).

Also, the examiner maintains that the holes ref. #12 form an acute angle with the surfaces denoted by ref. #6 and ref. #4, and that the hole ref. #12 is not orthogonal to these surfaces.

The rejections are deemed proper.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

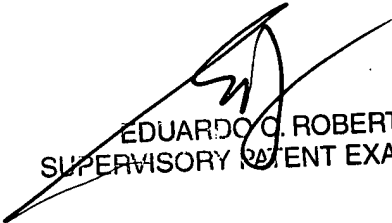


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER